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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/891,093	06/25/2001	Sidney Pestka	PBLI-P08-005	9195

28120 7590 09/30/2002

ROPES & GRAY  
ONE INTERNATIONAL PLACE  
BOSTON, MA 02110-2624

EXAMINER

MERTZ, PREMA MARIA

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 09/30/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. <b>09/891,093</b>	Applicant(s) <b>Sidney Pestka</b>
	Examiner <b>Prema Mertz</b>	Art Unit <b>1646</b>

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1)  Responsive to communication(s) filed on Sep 19, 2001
  - 2a)  This action is FINAL.      2b)  This action is non-final.
  - 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.
- Disposition of Claims**
- 4)  Claim(s) 18-20, 37, and 38 is/are pending in the application.
  - 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
  - 5)  Claim(s) \_\_\_\_\_ is/are allowed.
  - 6)  Claim(s) 18-20, 37, and 38 is/are rejected.
  - 7)  Claim(s) \_\_\_\_\_ is/are objected to.
  - 8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_\_ is/are a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12)  The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a)  The translation of the foreign language provisional application has been received.
- 15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1)  Notice of References Cited (PTO-892)
- 2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). 7
- 4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5)  Notice of Informal Patent Application (PTO-152)
- 6)  Other: \_\_\_\_\_

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## **DETAILED ACTION**

1. The preliminary amendment (Paper No. 5, 9/19/01) has been entered.

### ***Specification***

- 2a. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. It is suggested that the title be amended to recite the specific product being claimed. i.e. modified interleukin-2.

- 2b. The ATCC No. on page 18, line 9 is missing.

Furthermore, on page 18, lines 8-9, the old address of ATCC in Rockville, MD is disclosed.

The new address is ATCC, 10801 University Boulevard, Manassas, VA 20110-2209.

Appropriate correction in the specification is required.

### ***Claim Objections***

3. Claim 38 is objected because of the following informalities:

Claim 38 is objected to because it recites "purified o homogeneity" rather than "purified to homogeneity".

### ***Claim Rejections - 35 USC § 112, first paragraph***

- 4a. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 18-20, 37-38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one

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skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Claims 18-20, 37-38 are genus claims. According to the claims, an IL-2 protein having one or more amino acid substitutions, deletions, insertions and/or additions in naturally occurring IL-2, is encompassed by the claims. The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. The specification and claims do not place any limit on the number of amino acid substitutions, deletions, insertions and/or additions in IL-2. Thus, the scope of the claim includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. The specification and claims do not provide any guidance as to what changes or modifications are encompassed by the claims. Structural features that could distinguish compounds in the genus from others in the IL-2 protein class are missing from the disclosure. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the claimed genus, and because the genus is highly variant, the recitation of "human IL-2 encoded by a gene from a diseased cell", alone is insufficient to describe the genus. One of skill in the art would reasonably conclude that

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the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

4b. Claims 18-20, 37-38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 18-20, 37-38, broadly encompass all IL-2 proteins comprising a modification of natural IL-2, said modified IL-2 encoded by a gene from a diseased cell. However, the specification is not enabled for a single IL-2 polypeptide having an amino acid sequence anything less than the natural IL-2. These properties of the modified IL-2 may differ structurally, chemically and physically from other known proteins.

The claimed invention encompasses modified IL-2 protein molecules not envisioned or described in the specification, and neither does the specification disclose how the recombinantly produced polypeptides can be distinguished from each other. There is not a single mutein IL-2 disclosed in the specification, which has specific properties which differ structurally, chemically and physically from other known IL-2 polypeptides. By application of the factors set forth in Ex parte Forman (230 USPQ 546 (Bd. Pat. App. & Int. 1986), and reiterated in In re Wands (858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)), which include (1) quantity of experimentation, (2) guidance presented, (3) the predictability of the art, and (4) the breadth of the claim, in the instant application, the quantity of experimentation to determine which other IL-2 polypeptides having the

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activity described in claim 37 are encompassed by the scope of the claims is undue, since the claims read on every recombinant IL-2 derived from diseased cells. Applicants have failed to disclose which disease cells have the gene for the modified IL-2. Since Applicant has failed to disclose such, it would entail undue experimentation to screen every possible type of diseased cell known to man to determine which diseased cell contains the gene for the modified IL-2. The specification does not provide the necessary information nor the guidance to enable a skilled artisan to make all the embodiments which would be encompassed by the scope of the claims since the claims do not recite the specific properties characteristic for the claimed polypeptide. The instant disclosure is clearly insufficient support under the first paragraph of 35 U.S.C. § 112 for claims which encompass every and all recombinant polypeptides having the activity described in claim 37 and being derived from diseased cells.

***Claim Rejections - 35 USC § 112, second paragraph***

5. Claims 18-20, 37-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 is vague and indefinite because it recites "is a modification of the natural human interleukin-2". The metes and bounds of the term "modification" are unclear because it encompasses substitutions, deletions, insertions and a combination of such.

Claim 18 recites the limitation "the natural human interleukin-2" in line 3. There is insufficient antecedent basis for this limitation in the claim.

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Claims 19-20 are vague and indefinite because they recite "derived from leukemic leukocytes" and "derived from human malignancies", respectively, but the metes and bounds of "derived" has not been provided in the specification. It is unclear what the term means and what protein is considered "derived" or how the protein is "derived. Furthermore, the claim recites "being a modification of the natural human interleukin-2", which is incorrect because the claimed interleukin-2 is also naturally occurring.

Claims 37-38 are rejected as vague and indefinite insofar as they depend on claim 18 for its limitations.

***Conclusion***

No claims are allowed.

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (703) 308-4229. The examiner can normally be reached on Monday-Friday from 8:00AM to 4:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*Prema Mertz*  
Prema Mertz Ph.D.  
Patent Examiner  
Art Unit 1646  
August 29, 2002